DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NOV 19 2004

Re: Oraqix
Docket No. 04E-0392

The Honorable Jon Dudas
Acting Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Acting Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 6,031,007 filed by Maillefer Instruments Trading S.a.r.l. under 35 U.S.C. § 156. The human drug product claimed by the patent is Oraqix (Lidocaine and Prilocaine), which was assigned NDA No. 21-451.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it does not represent the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in *Glaxo Operations UK Ltd. v. Quigg*, 706 F. Supp. 1224 (E.D. Va. 1989), *aff'd*, 894 F. 2d 392 (Fed. Cir. 1990). The active ingredients for Oraqix are Lidocaine and Prilocaine. Lidocaine was previously approved for use in many products, including the product with the proprietary name, Octocaine, which was approved prior to January 1, 1982. In addition, the active ingredient Prilocaine was previously approved in combination with Lidocaine on February 4, 1998, in the product having the proprietary name EMLA.

The NDA was approved on December 19, 2003, which makes the submission of the patent term extension application on February 17, 2004, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the *Federal Register*, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: James B. Bieber
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